NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE LABORATORIES INC.,	:	**Civil Action No.: 03-4436(MLC)**
Plaintiff,	:	
v.	:	
NOSTRUM PHARMACEUTICALS INC.,	:	
Defendant.	:	**MEMORANDUM OPINION**

HUGHES, U.S.M.J.

This matter is before the Court upon the Motion of the Plaintiff, Shire Laboratories, Inc. ("Plaintiff" or "Shire"), to Amend the Scheduling Order to allow limited additional expert discovery pursuant to FED. R. CIV. P. 16. Defendant, Nostrum Pharmaceuticals Inc., ("Defendant" or "Nostrum") opposes the Motion. The Court reviewed the written submissions of the parties and conducted oral argument on October 3, 2005. For the reasons that follow, the Plaintiff's Motion is granted, subject to certain limitations and conditions.

I. BACKGROUND AND PROCEDURAL HISTORY

Shire is the owner of a New Drug Application ("NDA"), No. 20-712, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. (Pl's Amended Complaint at 3, ¶ 7). Nostrum submitted an Abbreviated New Drug

Application ("ANDA"), No. 76-697, to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of an extended-release capsule containing carbamazepine at 300 mg strength. (Pl's Amended Complaint at 3, ¶ 8). On July 29, 2003, Nostrum sent Shire a "Notification Pursuant to § 505(j)(2)(B)(ii) of the FDCA and 21 C.F.R. § 314.95". *Id.* at 3, ¶ 9. On July 5, 1994, Pharmavene, Inc. ("Pharmavene") received the '570 patent entitled Advanced Drug Delivery System and Method of Treating Psychiatric, Neurological and Other Disorders with Carbamazepine. *Id.* at 3, ¶ 11. Shire became the owner of this patent when Pharmavene merged with, and into, Shire. *Id.* Nostrum subsequently submitted a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use or sale of carbamazepine extended-release capsules before the expiration of the '570 patent. *Id.* at 4, ¶ 13.

Shire alleges that Nostrum's ANDA, with the paragraph IV certification for the '570 patent, and "for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '570 patent, is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Shire argues that Nostrum's Notice Letter, which states that the '570 patent was not infringed, provided "insufficient information regarding Nostrum's proposed drug product that is the subject of ANDA 76-697." (Pl's Amended Complaint at 5, ¶ 16). Shire further claims that until it receives the appropriate information it cannot "evaluate, confirm or test the correctness of Nostrum's certification that the '570 patent has not and would not be infringed." *Id.* It also alleges that Nostrum's "commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug

product that is the subject of ANDA 76-697, an extended-release capsule containing 300 mg of carbamazepine, will infringe one or more claims of the '570 patent." *Id.* at 5 ¶ 17).

Nostrum opposes Shire's allegations, arguing that they "constitute patent misuse because they are an attempt to extend Plaintiff's patents beyond their legal and permissible scope and because Plaintiff is seeking to use its patents to eliminate legitimate competition from Defendant's product." (Def's Answer at 3, ¶ 22). Nostrum also claims that its carbamazepine product does not infringe the '570 Patent held by Shire. *Id*. at ¶ 23. Nostrum counterclaims seeking a declaration that the '570 Patent is not infringed by Nostrum's ANDA product. *Id.* at 4, ¶ 4. Nostrum also claims that Plaintiff had a "full and fair opportunity to make a reasoned, good-faith determination of infringement," prior to filing the complaint and between the filing of the Complaint and service of the Complaint, but failed to do so. *Id.* at 7, ¶'s 19-22.

On April 15, 2004, an initial Scheduling Order was issued. It was subsequently amended three times, with the last change implemented on February 16, 2005. On December 10, 2004, Nostrum filed a notice of motion for summary judgement of non-infringement of the '570 patent. In preparation for the summary judgment motion, Shire discovered a document, which purports to show that Nostrum's product was possibly composed of "three physically distinct units." (Pl's Ltr. 09/01/05 at 3). This contradicts what Nostrum has "consistently maintained through [the] litigation[,] that its formulation uses 'a single type of uncoated substantially homogenous bead containing carbamazepine dispersed throughout the bead.'" *Id.* at 7.

Judge Cooper conducted oral argument on Defendant's Motion for Summary Judgment on July 15, 2005. At oral argument, the parties discussed this document and Judge Cooper noted that "[Shire] will need expert testimony, it seems to me, on the issue of literal infringement and

bearing upon issues of Doctrine of Equivalents." (Pl's Exhibit 4 at 147, lines 1 - 3).

Subsequent to the above oral argument, Plaintiff submitted an Application to Modify the Scheduling Order to allow "limited supplement expert reports" (Pl's Ltr. 09/01/05 at 1), pursuant to FED. R. PROC. 16, to address the claims in the above-referenced document. Shire argues that this request is only necessary, and the supplemental expert report will only be used, if Judge Cooper accepts Nostrum's claim construction that its product is composed of *one homogeneous bead unit as opposed to three distinct bead units*. In such event, Shire wants to perform testing on Nostrum's product to determine if it is composed of three distinct units or one homogeneous unit. (Pl's Brief at 1, 3-4). Nostrum opposes this motion, stating that no good cause exists to amend the scheduling order, as is required under FED. R. PROC. 16. (Def's Opp. Ltr. at 2).

II. DISCUSSION

Plaintiff claims that there is good cause to amend the Scheduling Order to allow additional expert testing of Nostrum's product and to allow the submission of an additional expert report to evaluate such testing. (Pl's Brief at 1). Defendant argues that not only is there a lack of good cause, but that Nostrum will suffer severe prejudice if Plaintiff's request is granted. (Def.'s Opp. Ltr. at 2). Because good cause exists, Plaintiff's Application to amend the scheduling order is granted, subject to the conditions below.

Rule 16 of the Federal Rules of Civil Procedure governs scheduling and management of cases. This Rule provides that:

> Except in categories of actions exempted by district court rule as inappropriate, the district judge, or a magistrate judge when authorized by district court rule, shall, after receiving the report from the parties under Rule 26(f) or after

> consulting with the attorneys for the parties and any unrepresented parties by a scheduling order that limits the time . . .
>
> (3) to complete discovery

See Eastern Minerals & Chems. Col. v Mahan, 225 *F.3d* 330, 340 *(*3d Cir. *2000)*. In the present case, Plaintiff's Motion for additional testing and submission of a new expert report would alter the existing Scheduling Order. A pre-trial Scheduling Order "shall not be modified except upon a showing of good cause and by leave of the District Judge, or, when authorized by local rule, by a Magistrate Judge." FED. R. PROC. 16.

A. Good Cause

A party can demonstrate good cause, pursuant to FED. R. PROC. 16, if they establish that the schedule "cannot reasonably be met despite [their] diligence." *Id. See* Commentary page 110-11; *See also*, *Globespanvirata, Inc. v. Texas Instruments Inc.*, 2005 U.S. Dist. LEXIS 16348 *5. Establishing good cause requires more than demonstrating a lack of prejudice to the nonmoving party. *Id.* at *9.(citations omitted). *In Enzo Life Sciences, Inc. v. Digene Corp*., 270 *F. Supp.* 2d 484, 490 (D.De. 2003), the court found good cause based on the fact that the Scheduling Order had already been modified several times to serve the interests of the parties and that the moving party "filed its amendment soon after it was able to satisfy the pleading requirements of Rule 9(b)." The Court found that the diligent filing of a motion seeking the amendment, combined with the lack of prejudice to the nonmoving party, established good cause under Rule 16. *Id.*

In the present case, Defendant filed a Motion for summary judgment on December 10, 2004. In preparing to defend against this Motion, Plaintiff identified the above referenced

document which rebuts Defendant's claims about product composition. Thus, Plaintiff's need to do the requested testing did not arise until after it learned of Defendant's claim construction and subsequently understood the value of the document discussing Nostrum's product composition as three distinct units. As is typical in patent infringement cases, the need for a specific expert opinion does not often crystalize until discovery has proceeded and dispositive motion briefing has occurred. Such is the case here.

At the summary judgment hearing, the above-referenced document identifying the composition of Defendant's product was introduced and its relevance discussed. Judge Cooper identified the need for expert discovery on the issue of literal infringement. The Judge stated, "[a]nd you would need expert testimony, it seems to me, on the issue of literal infringement and bearing upon issues of Doctrine of Equivalents." (July 15, 2005 Transcript of Motion Hearing, Page 147, lines 1 to 3). Whether Judge Cooper's comments reference the need for the documents' admittance into evidence or to the instant motion, the need for expert evaluation in this area of product composition was identified and justifies a finding of good cause to amend the Scheduling Order.

Alternatively, Plaintiff also claims that it meets the good cause standard because it has diligently proceeded with discovery throughout the course of litigation and only makes the instant request based on the document discovered during the summary judgment proceedings. (Pl's Ltr. 09/01/05 at 5). Plaintiff states that upon uncovering the document, which identifies Nostrum's product as containing three separate units, it immediately disclosed the information to the Court and to Defendant. *Id.* If accurate, the information in the document presents a significant means of rebuttal to Defendant's claim that its product is composed of one

homogeneous unit. Judge Cooper has yet to rule on Defendant's claim construction. Only if Defendant's single homogenous unit theory is accepted, will Plaintiff need to use the supplemental testing information, and then, only for rebuttal purposes. Thus, it is needed in a very limited context, and not, for example, to set forth a new cause of action.

Defendant argues that Plaintiff does not demonstrate good cause because it was not diligent in its discovery efforts. If it had been, Defendant claims it would have addressed the "newly discovered" document much earlier in the process as it was presented to Plaintiff in September 2004. (Def's Response at 3). In addition, Defendant claims that Plaintiff is precluded from using any test results as per the preclusion order from the August 19, 2004 conference call before Judge Hughes. (August 19th Transcript, page 9 line 12 to page 10 line 1). Nostrum also argues that Plaintiff is trying to supplement its expert report merely to belatedly revise its initial opinions of its expert.

The Court concludes that, while Plaintiff may have been in possession of the document identifying the composition of Defendant's product prior to its preparation to defend against Defendant's Motion for Summary Judgment, the importance of that document was not necessarily evident prior to Defendant's proffered claim construction.

Accordingly, Plaintiff has demonstrated good cause and the Court will permit a modification to the Scheduling Order to permit limited testing and submission of a supplemental expert report to determine if Defendant's product is composed of *one homogeneous bead unit as opposed to three distinct bead units*.

B. Prejudice

The Court also considers any potential prejudice to the non-moving party in determining

whether or not to grant a Motion to Amend a Scheduling Order. *Enzo Life*, 270 *F. Supp.* 2d at 490. In the present case, Defendant will suffer minimal prejudice if the Motion is granted. The new testing and additional expert report is only needed to rebut Defendant's claim construction that its product is composed of "a single type of uncoated substantially homogenous bead containing carbamazepine dispersed throughout the bead," and may only be admitted for this limited purpose. *Id.* at 7. (Pl's Ltr. 09/01/05 at 3). Should Judge Cooper reject the above claim construction, the new testing and accompanying expert report will not be necessary and will not be considered.

Further, Plaintiff will be required to produce all of its product testing, previously withheld, to Defendant. Therefore, both Defendant and Plaintiff will have unlimited access to each other's related product testing and accompanying export reports. This will ensure that the Court can decided the case with all of the relevant product composition information before it. It will also eliminate the element of surprise that could cause unfair prejudice to either side.

Finally, Defendant will not suffer prejudice based on claims of increased costs associated with further testing. If the additional testing and discovery generates unreasonable costs to Defendant, it may seek relief from the Court for some cost allocation of those expenses.

Accordingly, the Court concludes Defendant will not suffer undue prejudice if Plaintiff is allowed to amend the Scheduling Order to include additional testing and an accompanying expert report.

C. Delay

As mentioned above, delay is also a factor to consider in determining whether the moving party has demonstrated good cause for amending a Scheduling Order. *Enzo Life*, 270 *F. Supp. 2d*

at 490. In the present case, no such substantial delay exists. Both parties' experts have yet to be deposed and the Court has scheduled a status conference on October 19, 2005 to discuss the procedure for any necessary *Markman* hearing and to set a dispositive motion schedule. Thus, delay is not a factor in Plaintiff's Motion to Amend the Scheduling Order.

III. CONCLUSION

For the reasons stated above, Plaintiff has demonstrated good cause to allow this Court to grant its Motion to Amend the Scheduling Order to allow additional testing of Defendant's product and to admit an expert report evaluating such testing. Plaintiff has been diligent in addressing its discovery concerns, no substantial prejudice will befall Defendant if the Motion is granted, and no significant delay will result from allowing the additional testing and the admittance of an accompanying expert report. As mentioned, such report will only be admitted to rebut Defendant's claim that its product is composed of "a single type of uncoated substantially homogenous bead containing carbamazepine dispersed throughout the bead," should such claim construction be approved by Judge Cooper. (Pl's Ltr. 09/01/05 at 3). In addition, Plaintiff must produce any product testing originally withheld from Defendant.

Therefore, Plaintiff's Motion to Amend the Scheduling Order to permit additional expert testing on Defendant's product and to submit an accompanying expert report is hereby granted. An appropriate Order accompanies this Memorandum Opinion.

October 7, 2005.